

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the reasons that follow.

Claims 16-29 remain pending in this application.

Interview

The undersigned wishes to thank Examiner Yaen for the courtesies extended to Messrs. Jerry Swiss and Bill Chan (assignee's representative) during the personal interview conducted on 14 June 2006 for this application. The Interview Summary accurately reflects the discussion held some of which is elaborated upon below.

Rejections under 35 U.S.C. § 112, 1st paragraph

Claims 16-19 are rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. Applicant notes that there is a discrepancy between the Office Action Summary and the Office Action itself. The Office Action Summary indicates that claims 16-29 are rejected, however, the Office Action (at page 2, paragraph 6) rejects only claims 16-19. Applicant requests clarification.

In support of the rejection, the Examiner states that “[t]he specification fails to provide a sufficient nexus between the administration of apoptotic bodies in the CHS model and the treatment of CHF.” Further, the Examiner argues that “one of skill in the art would require additional guidance in the form of a working example that show the treatment of CHF, wherein the administration of apoptotic bodies altered the Th2 immune response as indicated.”

Applicant submits that claims 16-19 (indeed 16-29, for the same reasons) are fully enabled, as evidenced by the enclosed Declaration by Dr. Arkady Mandel, M.D., Ph.D., D. Sc. Dr. Mandel concludes, at paragraph 9 of his Declaration, that

It is my opinion that the literature cited above, evidences that decreases in pro-inflammatory cytokines and/or increase in anti-inflammatory cytokines would correlate to treatment protocols for CHF. Based on the evidence in U.S. Serial no. 09/866,569, Examples 1 and 2 that show a decrease in inflammation in the CHS assay using the claimed methods, the skilled artisan, in view of the cited literature and the teachings of the present application, would correlate these results from the CHS model to treatment of CHF.

Dr. Mandel bases his conclusion on several facts that would have been known to one of ordinary skill in the art. First, contact hypersensitivity (CHS) is a Th-1 cell-mediated inflammatory disorder involving inflammatory cytokines such as IL-1, TNF- α and IFN- γ and that the degree of inflammation associated with CHS is decreased by anti-inflammatory cytokines such as IL-10 (Mandel Declaration at ¶ 4). Second, inflammatory cytokines, such as IL-1 β , TNF- α and IL-6 play a role in the pathophysiology of congestive heart failure (CHF), characterized by increased circulating levels of these inflammatory cytokines as well as enhanced expression of inflammatory mediators such as TNF- α and IL-6 within the failing myocardium (Mandel Declaration at ¶ 5). Third, IL-10 is able to downregulate pro-inflammatory cytokines such as IL-1 β and TNF- α (Mandel Declaration at ¶ 8). Indeed, a decrease in IL-10 levels as well as a decrease in the IL-10 to TNF- α ratio has been correlated with depressed cardiac function in heart failure in rats (Mandel Declaration ¶ 7). Finally, an immunoglobulin-based treatment for patients suffering from CHF, has been shown to increase IL-10 with a slight decrease in TNF- α and IL-1 β (Mandel Declaration at ¶ 8).

Thus on balance, the prior art demonstrates a connection between decreasing pro-inflammatory cytokines and/or increasing anti-inflammatory cytokines and the treatment of CHF. The specification of the present application demonstrates a diminishment in CHS, known to be mediated by pro-inflammatory cytokines. Accordingly, Applicant submits that the specification provides sufficient nexus between the administration of apoptotic bodies in the CHS model and the treatment of CHF and that one of ordinary skill in the art would require no additional guidance to administer the apoptotic bodies of the invention for the treatment of CHF. Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 112, 1st paragraph.


Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

Date 20 September 2006

By 

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